

93. A method for detecting a lysosomal storage disorder (LSD), comprising assaying LAMP-1 in a sample of blood obtained from a patient that is asymptomatic for a LSD, an increase in the level of LAMP-1 in the patient relative to the corresponding level of LAMP-1 in a non-affected individual or population being indicative of a LSD.

94. ☒ Cancel

REMARKS

The paragraph numbering of the office action is used in responding to the Examiner's remarks. Claim amendments should not be construed as an acquiescence in any ground of rejection.

3. Claims 52-53, 55-74 and 93-94 stand rejected for lack of enablement. However, the Examiner acknowledge that the claims are neabled for detecting increases in Lamp-1 expression, 4-sulphatase activty, acid phosphatase activity, beta hexosaminidase activity and alpha-mannosidase activity and correlating an increase with an LSD. The claims havê been amended to refer to the subject matter that the Examiner agrees is enabled.

4. The Examiner asks what is meant by the acronyms LAMP-1, LAMP-II or LIMP-II. Applicants have inserted in parentheses what LAMP-1 stands for in claim 52. The other terms are not used in the amended claims.

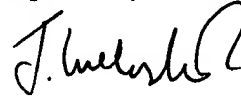
The Examiner also says that the term "immunointeractive molecule" is unclear but applicants have supported for antibodies or antigen binding fragments thereof. The claims have been amended to refer to antibodies. It is noted that the specification defines antibodies is such a manner that the term is generic to whole antibodies and their binding fragments.

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If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,



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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**IN THE CLAIMS:**

Claim 52 has been amended as follows:

52. (Twice amended) A method of detecting a lysosomal storage disorder (LSD), monitoring the progress of a LSD or the efficacy of treatment of a LSD in a human or animal subject, the method comprising assaying the level of a LSD marker in a biological sample derived from the subject, wherein the LSD marker is selected from the group consisting of Lamp-1 (lysosome-associated membrane protein type-1), ~~Lamp-2, Lamp-H, mannose 6-phosphate receptors,  $\alpha$ -L-iduronidase,~~ 4-sulphatase, acid phosphatase (ACP),  $\beta$ -hexosaminidase, and  $\alpha$ -mannosidase,, ~~a difference~~ an increase in the level of the LSD marker in the subject relative to the corresponding level of the LSD marker in a non-affected individual or population being indicative of a LSD.

Claims 53, 56 and 57 have been canceled.

Claim 66 has been amended as follows:

66. (Twice amended) The method according to claim 52, wherein the step of assaying the level of a LSD marker comprises contacting the biological sample with one or more ~~immunointeractive molecules~~ antibodies specific for said LSD marker for a time and under conditions sufficient for the formulation of a complex to occur.

Claim 67 has been canceled.

Claim 68 has been amended as follows:

68. (Amended) The method according to claim 67, wherein ~~the antibody molecule is a monoclonal antibody that binds to the LSD marker~~ the one or more antibodies are monoclonal antibodies.

Claim 69 has been amended as follows:

69. (Amended) The method according to claim 66, wherein the ~~immunointeractive molecule~~ one or more antibodies is/are labeled with a reporter molecule.

Claim 70 has been amended as follows:

70. (Amended) The method according to claim 66, further comprising the step of contacting ~~the~~ a complex formed between the LSD marker and ~~the immunointeractive molecule~~ one of the one or more antibodies with a labeled ~~immunointeractive molecule~~ antibody for a time and under conditions sufficient for binding to occur.

Claim 71 has been amended as follows:

71. (Amended) The method according to claim 70, wherein the labeled ~~immunointeractive molecule~~ antibody is labeled with a reporter molecule.

Claim 74 has been amended as follows:

74. (Once amended) The method according to claim 52, wherein:

- (a) the LSD is selected from the list set forth in Table 1;
- (b) the LSD marker is ~~selected from the group consisting of~~ LAMP-1, ~~LAMP-2, and LAMP-II~~;
- (c) the biological sample comprises blood, serum or urine; and
- (d) the assay comprises measuring the enzymatic activity of the LSD marker or is an immunoassay.

Claim 93 has been amended as follows:

93. (Once amended) A method for detecting a lysosomal storage disorder (LSD), comprising assaying LAMP-1, ~~LAMP-2 or LAMP-II~~ in a sample of blood obtained from a patient that is asymptomatic for a LSD, ~~a difference~~ an increase in

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the level of LAMP-1, ~~LAMP-2 or LAMP-H~~ in the patient relative to the corresponding level of LAMP-1, ~~LAMP-2 or LAMP-H~~ in a non-affected individual or population being indicative of a LSD.

Claim 94 has been canceled.

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